UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,646	07/19/2006	Robertus Mattheus Felix Van Der Weiden	2007-1006-1	7719

466 7590 06/01/2010

YOUNG & THOMPSON
209 Madison Street
Suite 500
Alexandria, VA 22314

EXAMINER	
DORNA, CARRIE R	
ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
06/01/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/586,646	VAN DER WEIDEN, ROBERTUS MATTHEUS FELIX	
	Examiner	Art Unit	
	Carrie Dorna	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-60,64,66,68-75 and 114-118* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-60,64,66,68-75 and 114-118* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 February 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to the Amendment filed 16 February 2010. The Examiner acknowledges the amendments to claims 54-60, 64, 66, 68-75, the cancellation of claims 61-63, 65, 67, 91-103, 105-107, and 110-111, as well as the addition of claims 114-118. Claims 54-60, 64, 66, 68-75, and 114-118 are now pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claims 115, 117, and 118** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 115 recites “the mat of material is attached to threads”. Claim 115 depends from claim 72, which recites “means for connection comprises at least one of: one or more threads…, or a mat of material”. Claim 72 depends from claim 54, which recites “a mat of material”. It is unclear whether the mat of claim 115 is referring to the mat of claim 72 and/or the mat of claim 54. Furthermore, it is unclear whether the threads of claim 115 are different from or the same as the threads of claim 72.

Claim 117 recites the limitation "the means for connection" in line 28. There is insufficient antecedent basis for this limitation in the claim.

Claim 118 is rejected as it is dependent on claim 117.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 54, 59, 60, 64, 66, 68, 72, and 116-118** are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,954,057 (Li).

Regarding **claim 54**, Li teaches an assembly for use in the attachment of a patient's vaginal apex or uterus or rectum to her/his spine, comprising a first tube (*Figure 23, housing,* 355) having a length adapted to a distance from an outer wall of the patient's abdomen to a sacrum (Device is capable of extending from the outer wall of the patient's abdomen to the sacrum as that distance depends on the dimensions of the patient's anatomy; col. 16, line 40), which first tube (355) is provided with a distal end capable of being brought into engagement with the sacrum and comprising an opposite proximal end and having a first passage (*Figure 23, passageway,* 370) from a distal to the proximal end thereof (col. 16, lines 41-43); a second tube (*Figure 23, shaft,* 378) having a length that at least equals a length of the first tube (355) (col. 16, lines 45-46), which second tube (378) is provided with a distal end and comprises an opposite proximal end; and at least one means for attachment (*Figure 22, suspension strap,* 315) provided with a distal end (*Figure 9, aperture,* 53 on *Figure 22, portion,* 325) for attachment to the sacrum and a proximal end (*Figure 22,* triangular portion of strap adjacent *portion,* 320) for attachment of an end of means for connection (*Figure 22,*

portion, 320) for connection to the patient's vaginal apex or uterus or rectum (col. 12, line 66-col. 13, line 4; col. 16, lines 4-10; col. 17, lines 33-37), wherein the distal end of the second tube (378) and the proximal end (triangular portion of strap adjacent *portion,* 320) of the means for attachment are formed for functional mutual engagement (see *Figure 23*), wherein the second tube (378) can be movably accommodated in the first tube (355) (col. 16, lines 41-43 and lines 48-50), the second tube or rod (378) extends into the first tube (355) and at least a part of the means for connection (320) is attached to the means for attachment (315) and situated within the first tube (355), the part of the means for connection (320) is situated between the first (355) and the second tube (378), the distal end of the second tube (378) is narrowed for together with the first tube (355) forming an accommodation space for said part of the means for connection (320) (col. 16, lines 55-61; see *Figure 23*), at least a part of the means for connection (320) is attached to the means for attachment (315) and is situated around the distal end of the second tube (378) (The term "around" is interpreted to mean "near"; col. 16, line 50-63), and a mat (*Figures 22 and 23, portion,* 325) is capable of being wrapped around the second tube (378) (col. 16, lines 4-8 and lines 50-63).

Regarding **claim 59**, Li teaches that the distal end of the second tube (*Figure 23, shaft,* 378) is formed for fittingly, holding the proximal end (*Figure 22,* triangular portion of strap adjacent *portion,* 320) of the means for attachment (*Figure 22, suspension strap,* 315) (col. 16, lines 50-62).

Regarding **claim 60**, Li teaches that the second tube (*Figure 23, shaft,* 378) has an internal cavity (*Figure 23, bore,* 380), which is at least formed at the distal end (col. 16, lines 50-51).

Regarding **claim 64**, Li teaches that the second tube (*Figure 23, shaft,* 378) has an internal cavity (*Figure 23, bore,* 380), which is at least formed at the distal end, and wherein the distal end of the second tube (378) forms an accommodation space for the proximal end of the means for attachment (*Figure 22, strap,* 315) and is provided with a passage to the side (*Figure 23, slot,* 381) (col. 16, 50-54), wherein an end portion of the said part of the means for connection (*Figure 22, portion,* 320), extends through the passage (381) (col. 16, line 50-63).

Regarding **claim 66**, Li teaches that the said part of the means for connection (*Figure 22, portion,* 320) comprises a mat of material capable of enabling bodily tissue ingrowth (mesh, col. 16, lines 4-8).

Regarding **claim 68**, Li teaches that the means for attachment (*Figure 22, strap,* 315) has a diameter that at least almost corresponds to the diameter of the first passage (*Figure 23, passageway,* 370) (see *Figure 23*).

Regarding **claim 72**, Li teaches that the means for connection (*Figure 22, portion,* 320) comprises a mat of material capable of enabling bodily tissue ingrowth (col. 16, lines 4-8).

Regarding **claim 117**, Li teaches an assembly for use in the attachment of a patient's vaginal apex or uterus or rectum to her/his spine, comprising: a first tube (*Figure 23, housing,* 355) having a length adapted to a distance from an outer wall of

the patient's abdomen to a sacrum (Device is capable of extending from the outer wall of the patient's abdomen to the sacrum as that distance depends on the dimensions of the patient's anatomy; col. 16, line 40), which first tube (355) is provided with a distal end to be brought into engagement with the sacrum and comprising an opposite proximal end and having a first passage (*Figure 23, passageway,* 370) from a distal to the proximal end thereof (col. 16, lines 41-43); a second tube (*Figure 23, shaft,* 378) having a length that at least equals a length of the first tube (355) (col. 16, lines 45-46), which second tube (378) is provided with a distal end and comprises an opposite proximal end; and at least one attachment device (*Figure 22, suspension strap,* 315) provided with a distal end (*Figure 9, aperture,* 53 on *Figure 22, portion,* 325) for attachment to the sacrum and a proximal end (*Figure 22,* triangular portion of strap adjacent *portion,* 320) for attachment of an end of a connector (*Figure 22, portion,* 320) to the patient's vaginal apex or uterus or rectum (col. 12, line 66-col. 13, line 4; col. 16, lines 4-10; col. 17, lines 33-37), wherein the distal end of the second tube (378) and the proximal end (triangular portion of strap adjacent *portion,* 320) of the attachment device are formed for functional mutual engagement (see *Figure 23*), wherein the second tube (378) can be movably accommodated in the first tube (355) (col. 16, lines 41-43 and lines 48-50), the second tube (378) extends into the first tube (355) and at least a part of the connector (320) is attached to the attachment device (315) and situated within the first tube (355), the part of the connector (320) is situated between the first (355) and the second tube (378), the distal end of the second tube (378) is narrowed for together with the first tube (355) forming an accommodation space for said part of the connector

(320) (col. 16, lines 55-61; see *Figure 23*), at least a part of the connector (320) is attached to the attachment device (315) and is situated around the distal end of the second tube (378) (The term "around" is interpreted to mean "near"; col. 16, line 50-63), and a mat (*Figures 22 and 23, portion,* 325) is capable of being wrapped around the second tube (378) (col. 16, lines 4-8 and lines 50-63).

Regarding **claims 116 and 118**, Li teaches that the means for connection (*Figure 22, portion,* 320) is capable of being completely positioned within the first tube (*Figure 23, housing,* 355) (col. 16, lines 55-61; see *Figure 23*).

6. **Claims 54-60, 64, 66, 68, 71, 72, 74, and 114-118** are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0028980 (Thierfelder et al.).

Regarding **claim 54**, Thierfelder et al. teaches an assembly for use in the attachment of a patient's vaginal apex or uterus or rectum to her/his spine, comprising a first tube (trocar, [0139]) having a length adapted to the distance from an outer wall of the patient's abdomen to a sacrum (Device is capable of extending from the outer wall of the patient's abdomen to the sacrum as that distance depends on the dimensions of the patient's anatomy), which first tube (trocar, [0139]) is provided with a distal end capable of being brought into engagement with the sacrum and comprising an opposite proximal end and having a first passage from a distal to the proximal end thereof (trocar necessarily has a lumen; [0139]), a second rod (*Figure 11, surgical article,* 40) having a length that at least equals a length of the first tube ([0072]; trocar, [0139]), which second rod (40) is provided with a distal end and comprises an opposite proximal end ([0072]);

and at least one means for attachment (*Figure 11, bone screw,* 44) provided with a distal end for attachment to the sacrum and a proximal end for attachment of an end of means for connection (*Figure 11, suture,* 43) to the patient's vaginal apex or uterus or rectum ([0072]-[0073]), wherein the distal end of the second rod (40) and the proximal end of the attachment means (44) are formed for functional mutual engagement ([0072]-[0073]; see *Figure 11*), wherein the second rod (40) can be movably accommodated in the first tube ([0072]-[0073]; trocar, [0139]), the second rod (40) extends into the first tube (trocar, [0139]) and at least a part of the means for connection (43) is attached to the means for attachment (44) and situated within the first tube ([0072]-[0073]; trocar, [0139]), wherein the said part of the means for connection (43) is situated between the first (trocar, [0139]) and the second rod (40) ([0072]-[0073]; trocar, [0139]; see *Figure 11*), the distal end of the second rod (40) is narrowed for together with the first tube (trocar, [0139]) forming an accommodation space for said part of the means for connection (43), at least a part of the means for connection (43) is attached to the means for attachment (44) and is situated around the distal end of the second rod (40) (see *Figure 11*; [0072]-[0073]; The term “around” is interpreted to mean “near”.), and a mat is capable of being wrapped around the second rod (40) (The suture 43 is considered to be the "means for connection". A portion of the suture 43 adjacent and attached to the bone screw 44 may be considered to be a “thread", while the remainder of the suture 43 may be considered to be a "mat". The suture 43 is formed of braided polyester, therefore this remainder of the suture 43 may considered to be a "mat of material enabling bodily tissue ingrowth", [0069].).

Regarding **claim 55**, Thierfelder et al. teaches that the second rod (*Figure 11, surgical article,* 40) can be rotatably accommodated in the first tube ([0072]-[0073]; trocar, [0139]).

Regarding **claim 56**, Thierfelder et al. teaches that the means for attachment (*Figure 11, bone screw,* 44) is a bone screw (0072]-[0073]).

Regarding **claim 57**, Thierfelder et al. teaches that the proximal end of the second rod (*Figure 11, surgical article,* 40) is provided with means for rotation of the second rod (40) (surgical article has a motorized driver for rotating the shaft to implant the bone screw, [0072]-[0073]).

Regarding **claim 58**, Thierfelder et al. teaches that the means for rotation comprises an arm that is transverse to the second rod (*Figure 11, surgical article,* 40) (motorized driver necessarily comprises an arm portion that is transverse to the shaft so that rotational energy is transferred to the shaft, [0072]-[0073]).

Regarding **claim 59**, Thierfelder et al. teaches that the distal end of the second rod (*Figure 11, surgical article,* 40) is formed for fittingly, holding the proximal end of the means for attachment (*Figure 11, bone screw*, 44) ([0072]-[0073]; [0139]).

Regarding **claim 60**, Thierfelder et al. teaches that the second rod (*Figure 11, surgical article,* 40) has an internal cavity, which is at least formed at the distal end (second rod necessarily has an internal cavity for containing the suture, see *Figure 11,* [0072]-[0073).

Regarding **claim 64**, Thierfelder et al. teaches that the second rod (*Figure 11, surgical article,* 40) has an internal cavity, which is at least formed at the distal end, and

wherein the distal end of the second rod (40) forms an accommodation space for the proximal end of the means for attachment (*Figure 11*, *bone screw,* 44) and is provided with a passage to the side (see *Figure 11*), wherein an end portion of the said part of the means for connection (*Figure 11, suture,* 43) extends through the passage (see *Figure 11*; [0072]-[0073]).

Regarding **claim 66**, Thierfelder et al. teaches that the said part of the means for connection (*Figure 11, suture,* 43) comprises a mat of material enabling bodily tissue ingrowth (The suture 43 is formed of braided polyester, therefore the suture 43 is considered to be a "mat of material enabling bodily tissue ingrowth", [0069]).

Regarding **claim 68**, Thierfelder et al. teaches that the means for attachment (*Figure 11, bone screw,* 44) has a diameter that at least almost corresponds to the diameter of the first passage (trocar lumen, [0139]).

Regarding **claim 71**, Thierfelder et al. teaches that the first tube (trocar, [0139]) is provided with a handle near the proximal end (trocar necessarily has some portion near the proximal end where the surgeon grips the trocar to manipulate it properly, [0139]).

Regarding **claim 72**, Thierfelder et al. teaches that the means for connection (*Figure 11, suture,* 43) comprises one or more threads that are attached to the attachment means (*Figure 11, bone screw,* 44) (The suture 43 is considered to be the "means for connection". A portion of the suture 43 adjacent and attached to the bone screw 44 may be considered to be a “thread", while the remainder of the suture 43 may be considered to be a "mat". The suture 43 is formed of braided polyester, therefore this

remainder of the suture 43 may considered to be a "mat of material enabling bodily tissue ingrowth", [0069]; [0072]).

Regarding **claim 74**, Thierfelder et al. teaches that the device is sterilely accommodated in hermetically closed packaging ([0067]).

Regarding **claim 114**, Thierfelder et al. teaches that the means for connection (*Figure 11, suture,* 43) comprise one or more threads (The suture 43 is considered to be the "means for connection". A portion of the suture 43 adjacent and attached to the bone screw 44 may be considered to be a “thread", while the remainder of the suture 43 may be considered to be a "mat". The suture 43 is formed of braided polyester, therefore this remainder of the suture 43 may considered to be a "mat of material enabling bodily tissue ingrowth", [0069]; [0072]).

Regarding **claim 115**, Thierfelder et al. teaches that the mat of material is attached to threads (The suture 43 is considered to be the "means for connection". A portion of the suture 43 adjacent and attached to the bone screw 44 may be considered to be a “thread", while the remainder of the suture 43 may be considered to be a "mat". The suture 43 is formed of braided polyester, therefore this remainder of the suture 43 may considered to be a "mat of material enabling bodily tissue ingrowth", [0069]; [0072]).

Regarding **claim 116**, Thierfelder et al. teaches that the means for connection (*Figure 11, suture,* 43) is capable of being completely positioned within the first tube (trocar, [0139]).

Regarding **claim 117**, Thierfelder et al. teaches an assembly for use in the attachment of a patient's vaginal apex or uterus or rectum to her/his spine, comprising a first tube (trocar, [0139]) having a length adapted to the distance from an outer wall of the patient's abdomen to a sacrum (Device is capable of extending from the outer wall of the patient's abdomen to the sacrum as that distance depends on the dimensions of the patient's anatomy), which first tube (trocar, [0139]) is provided with a distal end capable of being brought into engagement with the sacrum and comprising an opposite proximal end and having a first passage from a distal to the proximal end thereof (trocar necessarily has a lumen; [0139]), a second rod (*Figure 11, surgical article,* 40) having a length that at least equals a length of the first tube ([0072]; trocar, [0139]), which second rod (40) is provided with a distal end and comprises an opposite proximal end ([0072]); and at least one attachment device (*Figure 11, bone screw,* 44) provided with a distal end for attachment to the sacrum and a proximal end for attachment of an end of a connector (*Figure 11, suture,* 43) to the patient's vaginal apex or uterus or rectum ([0072]-[0073]), wherein the distal end of the second rod (40) and the proximal end of the attachment means (44) are formed for functional mutual engagement ([0072]-[0073]; see *Figure 11*), wherein the second rod (40) can be movably accommodated in the first tube ([0072]-[0073]; trocar, [0139]), the second rod (40) extends into the first tube (trocar, [0139]) and at least a part of the connector (43) is attached to the attachment device (44) and situated within the first tube ([0072]-[0073]; trocar, [0139]), the part of the connector (43) is situated between the first (trocar, [0139]) and the second rod (40) ([0072]-[0073]; trocar, [0139]; see *Figure 11*), the distal end of the second rod (40) is

narrowed for together with the first tube (trocar, [0139]) forming an accommodation space for said part of the means for connection (43), at least a part of the connector (43) is attached to the attachment device (44) and is situated around the distal end of the second rod (40) (see *Figure 11*; [0072]-[0073]; The term “around” is interpreted to mean “near”.), and a mat is capable of being wrapped around the second rod (40) (The suture 43 is considered to be the "means for connection". A portion of the suture 43 adjacent and attached to the bone screw 44 may be considered to be a “thread", while the remainder of the suture 43 may be considered to be a "mat". The suture 43 is formed of braided polyester, therefore this remainder of the suture 43 may considered to be a "mat of material enabling bodily tissue ingrowth", [0069].).

Regarding **claim 118**, Thierfelder et al. teaches that the connector (*Figure 11, suture,* 43) is capable of being completely positioned within the first tube (trocar, [0139]).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. **Claim 69** is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,954,057 (Li) in view of U.S. Patent Application Publication No. 2002/0143234 (LoVuolo).

Regarding **claim 69**, Li teaches all of the limitations of claim 54 above (see discussion for claim 54). Li does not teach that the assembly comprises gauge means.

However, LoVuolo teaches a device for suspending a bodily structure comprising a first tube (*Figure 2, cannula,* 18) that is provided with means for gauging (*Figure 2, stripes,* 44) related to the sliding of a second tube (*Figure 2, deploying rod,* 28) in the first tube (*cannula,* 18) corresponding to an attachment length of the distal end of the means for attachment (*Figure 2, anchor toggle,* 32) (Depth calibration stripes indicate the insertion depth of the cannula, which allows the surgeon to accurately access when the cannula is in the appropriate location to then deploy the anchor using the deploying rod, [0047], 0048], [0057]. Therefore, the stripes are related to the insertion depth of the second tube and the length of the sutures attached to the anchor, which is directly related to the tension of the organ suspension). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the gauge means of LoVuolo on the second tube of Li, because depth indicia allow the surgeon to accurately access when the delivery mechanism is in the appropriate location to then deploy the anchoring device (LoVuolo, [0057]).

9. **Claim 69** is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0028980 (Thierfelder et al.) in view of U.S. Patent Application Publication No. 2002/0143234 (LoVuolo).

Regarding **claim 69**, Thierfelder et al. teaches all of the limitations of claim 54. Thierfelder et al. does not teach that the assembly comprises means for gauging.

However, LuVuolo teaches a device for suspending a bodily structure comprising a first tube (*Figure 2, cannula,* 18) that is provided with means for gauging (*Figure 2, stripes,* 44) related to the sliding of a second tube (*Figure 2, deploying rod,* 28) in the first tube (*cannula,* 18) corresponding to the attachment length of the distal end of the attachment means (*Figure 2, anchor toggle,* 32) (Depth calibration stripes indicate the insertion depth of the cannula, which allows the surgeon to accurately access when the cannula is in the appropriate location to then deploy the anchor using the deploying rod, [0047], 0048], [0057]. Therefore, the stripes are related to the insertion depth of the second tube and the length of the sutures attached to the anchor, which is directly related to the tension of the organ suspension). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the means for gauging of LuVuolo on the second tube of Thierfelder et al., because depth indicia allow the surgeon to accurately access when the delivery mechanism is in the appropriate location to then deploy the anchoring device (LuVuolo, [0057]).

10. **Claims 70 and 73** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,954,057 (Li) in view of U.S. Patent No. 5,458,606 (Wortrich).

Regarding **claims 70 and 73,** Li teaches all of the limitations of claim 54 above. Li does not teach that the distal end of the first tube is serrated, nor does Li teach the use of a laparoscope.

However, Wortrich teaches a system for implanting a surgical tack in the sacrum to suspend a prolapsed pelvic organ that comprises a first tube having a serrated distal edge, and a laparoscope. It would have been obvious to one of ordinary skill in the art at

the time of the invention to provide the laparoscope of Wortrich in the assembly of Li, because the laparoscope allows the surgeon to observe the surgical cavity remotely reduce patient recovery time, pain, and trauma (Wortrich, col. 1, lines 16-21 and col. 3, lines 63-67). Furthermore, It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a serrated edge on the distal tip of the first tube of Li as taught by Wortrich, because the serrated edge provides better engagement with the surface in which the attachment mechanism is to be placed (Wortrich, col. 6, lines 32-37).

11. **Claims 70, 73, and 75** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0028980 (Thierfelder et al.) in view of U.S. Patent No. 5,458,606 (Wortrich).

Regarding **claims 70, 73, and 75**, Thierfelder et al. teaches all of the limitations of claims 54 and 74. Thierfelder et al. does not teach that the distal end of the first tube is serrated, nor does Thierfelder et al. teach the use of a laparoscope or viewing screen.

However, Wortrich teaches a system for implanting a surgical tack in the sacrum to suspend a prolapsed pelvic organ that comprises a first tube having a serrated distal edge, a laparoscope, and a viewing screen that is functionally connected to the laparoscope. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the laparoscope and viewing screen of Wortrich in the assembly of Thierfelder et al., because the laparoscope and viewing screen allows the surgeon to observe the surgical cavity remotely reduce patient recovery time, pain, and trauma (Wortrich, col. 1, lines 16-21 and col. 3, lines 63-67). Furthermore, It would have been

obvious to one of ordinary skill in the art at the time of the invention to provide a serrated edge on the distal tip of the first tube of Thierfelder et al. as taught by Wortrich, because the serrated edge provides better engagement with the surface in which the attachment mechanism is to be placed (Wortrich, col. 6, lines 32-37).

Double Patenting

12. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

13. Applicant is advised that should claims 54 and 116 be found allowable, claims 117 and 118 will be objected to under 37 CFR 1.75 as being substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Response to Arguments

14. Applicant's arguments with respect to at least claims 54, 61-63, 65, and 67 regarding Thierfelder et al. have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that Thierfelder et al. does not teach the limitations of amended claim 54. While the Examiner does not necessarily find

Applicant's arguments persuasive, the Examiner has applied new grounds of rejection citing a new interpretation of Thierfelder et al. in view of the claim amendments.

15. In response to applicant's argument that the mat of Li is not wrapped around the second tube and thus contained completely within the first tube, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carrie Dorna whose telephone number is (571) 270-7483. The examiner can normally be reached on Monday - Friday from 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/C. D./
Examiner, Art Unit 3735